K010035

APR - 4 2001

510(k) Summary of Safety and Effectiveness

SUBMITTER: US Surgical a Division of Tyco Healthcare Group L.P.
150 Glover Avenue
Norwalk, CT 06856

CONTACT PERSON: Chester McCoy

DATE PREPARED: March 21, 2001

PROPRIETARY NAME: I.V.S. Tunneller

PREDICATE DEVICES: Tension Free Vaginal Tape (TVT) System (K974098)

DEVICE DESCRIPTION: The I.V.S. Tunneller is composed of three components: a stainless steel introducer, a polypropylene stylette and mesh.

The mesh used (SurgiPro™) is a non-absorbable, inert, sterile, porous surgical mesh knitted from multi-filament yarns of a polypropylene polymer from which SurgiPro surgical sutures are manufactured. The mesh measures approximately 0.44mm (0.17") in thickness and exhibits high burst strength and tensile strength in the form of a surgical suture. Synthetic polypropylene is reported to resist tensile strength loss indefinitely in tissue. SurgiPro mesh is knitted in such a fashion as to interconnect each multi-filament yarn and provide bi-directional elasticity.

SurgiPro mesh is used to repair or reinforce defects following surgery or trauma and serves to provide additional support to such wounds during the wound healing period. Animal studies have shown that the polypropylene filaments from which this mesh is manufactured elicit a minimal acute inflammatory reaction in tissue which is then followed by gradual encapsulation by fibrous tissue. Ingrowth of this fibrous tissue is permitted by the porosity of the knitted mesh structure.

INTENDED USE: The I.V.S. Tunneller is intended to be used in females to position a polypropylene mesh for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse.

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TECHNOLOGICAL CHARACTERISTICS:	Technologically both the new device and predicate device are the same (i.e. both are meshes that provide pubourethral support). Any differences in the two devices do not raise new questions of safety and effectiveness.
PERFORMANCE CHARACTERISTICS:	Results of clinical studies were used to show the I.V.S. Tunneller functioned as clinically intended
CONCLUSION:	Based on the information provided with the 510(k), we conclude this device is substantially equivalent to the existing legally marketed device under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Chester McCoy
Program Manager, Regulatory Affairs
United States Surgical
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K010035
Trade Name: IVS Tunneller
Regulatory Class: II
Product Code: FTL
Dated: July 31, 2000
Received: January 4, 2001

Dear Mr. McCoy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number ~~K003446~~ K010035

Device Name: I.V.S. Tunneller

Indications for Use: The I.V.S. Tunneller is intended to be used in females to position a polypropylene mesh for the treatment of genuine stress urinary incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over The Counter Use ____
(Per 21 CFR 801.109)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number ~~K003446~~ K010035